K123500
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) SUMMARY

MAY 2 2013

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   November 8, 2012 (Updated: March 22, 2013)

6. **TRADE NAME(S):**
   Aquilion LB Triton, TSX-201A/2, v4.91

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography

10. **PERFORMANCE STANDARD:**
    This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

11. **PREDICATE DEVICE:**

Product	Marketed by	510(k) Number	Clearance Date
Aquilion LB CT Scanner TSX-201A	Toshiba America Medical Systems	K050458	March 10, 2005
Aquilion ONE TSX-301A/2, w/4.74ER (Dose Reduction Technology)	Toshiba America Medical Systems	K113466	April 10, 2012

12. REASON FOR SUBMISSION:
Modification of a cleared device

13. DEVICE DESCRIPTION:
The Aquilion LB Triton, TSX-201A/2, v4.91 is a whole body CT scanner. This device captures cross sectional volume data sets. The device consists of a gantry, patient couch (table) and peripheral cabinets used for data processing and display.

14. SUMMARY OF INTENDED USES:
This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

15. SUBSTANTIAL EQUIVALENCE:
This device is substantially equivalent to the Aquilion LB CT Scanner, TSX-201A, K050458, marketed by Toshiba America Medical Systems. The Aquilion LB Triton, TSX-201A/2, v4.91, includes modifications to the cleared device which improves image reconstruction speed and includes the addition of optional software features. There is no change to the imaging chain in the gantry. The method of operation, base software and manufacturing process remain unchanged from the cleared device.

Additionally, this device is substantially equivalent to the Aquilion ONE TSX-301A/2, w/4.74ER, K113466, in that it includes the previously cleared dose reduction technology, AIDR 3D.

Summary of Changes:

Item	**Aquilion LB Triton TSX-201A/2, v4.91**	Aquilion LB CT Scanner TSX-201A (K050458)	Aquilion ONE TSX-301A/2, w/4.74ER (K113466)
Image reconstruction (maximum speed)	22 images per second	12 images per second	30 images per second
X-ray Generator Output Power	72kW Maximum	60kW Maximum	70kW Maximum
Dose Reduction	SureExposure 3D	Real EC	SureExposure 3D
Noise Reduction Processing	QDS AIDR 3D	N/A	QDS AIDR 3D
Console	• 2.53 GHz CPU Clock Frequency • 12 GB or more CPU Memory • DVD Drive	• 2 GHz CPU Clock Frequency • 2 GB or more CPU Memory • CD Drive	• 3.0 GHz CPU Clock Frequency • 8 GB or more CPU Memory • DVD Drive

1. Increased image reconstruction speed
2. High voltage generator is increased
3. Noise reduction processing software is now a standard feature
4. The computer console has been upgraded, which includes a faster CPU, additional CPU memory, a DVD Drive.
5. An optional Display Console Kit is now available.
6. Previously cleared software options are being added

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the following standards: IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-1-8, IEC60601-1-9, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18 and NEMA XR-25.

Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

17. TESTING

There is no change to the imaging chain in the gantry (i.e. geometry, detector/DAS, tube, beam limiting device). Image comparison data using brain, chest, abdomen and pelvis anthropomorphic phantoms, utilizing clinical scan conditions and reconstruction parameters, demonstrated that the subject device produces substantially equivalent images of representative structures as compared to the predicate device, Aquilion LB CT Scanner TSX-201A.

An image quality metrics study utilizing phantoms validated that the subject device is substantially equivalent to the predicate device (Aquilion LB CT Scanner TSX-201A) with regard to spatial resolution, CT number and contrast-to-noise ratio, uniformity, noise properties and low contrast resolution.

Additionally, representative diagnostic images including brain, chest, abdomen and peripheral exams were obtained using the subject device which demonstrates that the device produces images of diagnostic quality and; therefore, performs as intended.

Testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems with satisfactory results.

18. CONCLUSION

The modifications incorporated into the Aquilion LB Triton, TSX-201A/2, v4.91 do not change the indications for use or the intended use of the device. Based upon this information, conformance to standards, application of design controls and the performance data presented in this submission, Toshiba America Medical Systems, believes that the Aquilion LB Triton, TSX-201A/2, v4.91, is substantially equivalent in safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
% Mr. Paul Biggins
Director, Regulatory Affairs
2441 Michelle Drive
TUSTIN CA 92780

Re: K123500
Trade/Device Name: Aquilion LB Triton, TSX-201A/2, v4.91
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 22, 2013
Received: March 28, 2013

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

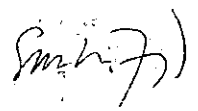
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123500

Device Name: Aquilion LB Triton, TSX-201A/2, v4.91

Indications for Use:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123500